K051509

JUL 27 2005

510K SUMMARY

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	Julie Stephens, President/Consultant Regulatory Resources Group, Inc.
Date Prepared:	May 31, 2005
Common Name:	Cryosurgical Unit and Accessories
Trade/Proprietary Name:	ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories
Classification Name:	Unit, Cryosurgical, Accessories (21 CFR 878.4350)
Product Code:	GEH, FAZ
Legally Marketed Predicate Device:	ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories - 510(k) Number: K934261

Device Description:

The ERBE USA, Inc. ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories is used to apply extreme cold to tissue during surgical procedures. It uses the Joule-Thompson principle where pressurized gas expands through a fine orifice producing a rapid drop in temperature and freezing the probe tip and the surrounding tissue. The unit is used with either N_2O (Nitrous Oxide) or CO_2 (Carbon Dioxide) gas. The unit and accessories are provided non sterile. The cryo probes are reusable and directions for cleaning and sterilizing the cryosurgical probes are provided in the Notes for Use.

Intended Use:

The ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories are intended for devitalization (destruction) of tissue during surgical procedures by the application of extreme cold and for removal of foreign bodies, mucous plugs, necrotic tissue, and tissue biopsy by cryoadhesion. Also see Clinical Indications.

510K SUMMARY

Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

Similarities

The ERBE USA, Inc. ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories has the same basic technology characteristics to induce extreme cold to tissue as the predicate unit and accessories, and the indications for use are the same except for the additions noted below under differences.

The ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories has the same "Indications for Use" stated in the 510(k) submission # K934261 which are as follows:

"For use with nitrous oxide (N_2O) or carbon dioxide (CO_2) and cryoprobes for cryosurgery."

"Clinical Indications:

Gynecology - Cervical erosions, Cervical polyps, Condylomas, Chronic Cervicitis, Vulva Carcinoma (palliative), Neoplasia

Dermatology - Leukoplakia, Fibroma, Condylomas, Basal Cell Carcinoma, Skin Tumor (palliative), Warts, Naephus

Ophthalmology Ablatio Retinae, Glaucoma, Lid Tumor

ENT - Leukoplakia, Inoperable Tumor (palliative), Laryngeal Papilloma, Fibroma, Angioma, Haemangioma

Thoracic Surgery - Post-Operative

Urology - Prostate Tumor (palliative), Condylomas, Penile Tumor (palliative)

Phlebology - Varicose Veins of the Lower Limbs (Cryo Stripping)

Proctology - Hemorrhoids (1st and 2nd Degree), Pari-Anal Condylomas, Anal Tumor (palliative), Rectal Tumor (palliative), Acute Anal Fissures

Pulmonology - Tumors, Granulomatous Tissue, Malignant Lesions (palliative)

Differences

The ERBE USA, Inc. ERBE ERBOKRYO® CA Cryosurgical probe (cryo probe) utilizes different materials from the predicate; however, the materials are biocompatible [see Section III, Declaration of Conformance with Consensus Standards]. The ERBE USA, Inc. ERBE ERBOKRYO® CA Cryosurgical unit has an added internal filter at the gas outlet in order to comply with the ASTM standard.

510K SUMMARY

The ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories have an expanded the indications for use. The difference to the indication is:

1. The addition of "for removal of foreign bodies, mucous plugs, necrotic tissue, and tissue biopsy by cryoadhesion."

2. The addition of "Pneumology: Tracheobronchial Stenoses (Cryorecanalization)"

All the ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories modifications were verified or validated in design control.

Conclusion:

The modifications to the ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories were minimal and comply with the current standards as documented under the "Declaration of Conformance with Consensus Standards".

All available/known studies involving "cryosurgical units" in conjunction with the expanded indications for use have been provided in this submission. The clinical documentation provided demonstrates that the ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories can be used safely and effectively to remove foreign bodies (*i.e.*, food such as peanuts, chicken bones, teeth, pills, mucus plugs, etc.) and tissue biopsy by cryoadhesion. The documentation also shows that the system can be used in Pneumology for Tracheobronchial Stenoses. The physicians consider cryotherapy to be a safe procedure for the treatment of bronchial wall tumors with minimal complications. Patients tolerate the procedure well and show improvement in symptoms at the end of the procedure. They also determined with malignant tumors that cryotherapy is a palliative treatment in these cases, and overall the results are favorable in between 70 and 80% measuring performance criteria (removal of obstruction >50% or not). Most of the studies did add the warning that because cryotherapy has a delayed effect in relieving bronchial obstructions it should not be used as emergency treatment in acute respiratory distress.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2005

ERBE USA, Inc.
c/o Ms. Julie Stephens
Regulatory Resources Group, Inc.
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K051509
Trade/Device Name: ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: June 2, 2005
Received: June 9, 2005

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051509

Device Name: ERBE ERBOKRYO® CA Cryosurgical Unit and Accessories

Indications For Use:

The ERBE ERBOKRYO® CA Cryosurgical Unit and accessories are intended for devitalization (destruction) of tissue during surgical procedures by the application of extreme cold and for removal of foreign bodies, mucous plugs, necrotic tissue, and tissue biopsy by cryoadhesion.

Clinical Indications for Cryosurgery

Gynecology	Cervical Erosions, Cervical Polyps, Condylomas, Chronic Cervicitis, Vulva Carcinoma (palliative), Neoplasia
Dermatology	Leukoplakia, Fibroma, Condylomas, Basal Cell Carcinoma, Skin Tumor (palliative), Warts, Naephus
Ophthalmology	Ablatio Retinae, Glaucoma, Lid Tumor
ENT	Leukoplakia, Inoperable Tumor (palliative), Laryngeal Papilloma, Fibroma, Angioma, Haemangioma
Thoracic Surgery	Post-Operative
Urology	Prostate Tumor (palliative), Condylomas, Penile Tumor (palliative)
Phlebology	Varicose Veins of the Lower Limbs (Cryo Stripping)
Proctology	Hemorrhoids (1st and 2nd Degree), Pari-Anal Condylomas, Anal Tumor (palliative), Rectal Tumor (palliative), Acute Anal Fissures
Pulmonology	Tumors, Granulomatous Tissue, Malignant Lesions (palliative)
Pneumology	Tracheobronchial Stenoses (Cryorecanalization)

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K051509